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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/798,218	03/10/2004	Marcel Thurk	02198/0200973-US0	3485

7278 7590 09/21/2005

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EXAMINER	
KOSAR, ANDREW D	
ART UNIT	**PAPER NUMBER**
1654	

DATE MAILED: 09/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/798,218	THURK, MARCEL	
	Examiner	Art Unit	
	Andrew D. Kosar	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 June 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* ~~is~~/are pending in the application.

4a) Of the above claim(s) *See Continuation Sheet* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *91,118 and 176* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

GST

Continuation of Disposition of Claims: Claims pending in the application are 1,17-19,23-26,50-52,56-59,82-84,88-90,117-119,163-165 and 169-176.
Continuation of Disposition of Claims: Claims withdrawn from consideration are 1,17-19,23-26,50-52,56-59,82-84,88-90,117,119,163-165 and 169-175.

DETAILED ACTION

Applicant is advised that Examiner Kosar is the examiner of record. Please direct all correspondences accordingly.

Applicant's response and amendments, filed June 28, 2005, is acknowledged.

Claims 1, 17-19, 23-26, 50-52, 56-59, 82-84, 88-91, 117-119, 123-126, 163-165, and 169-176 are pending.

Claims 1, 17-19, 23-26, 50-52, 56-59, 82-84, 88-90, 119, 123, 125, 126, 163-165, and 169-171 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim, for the reasons of record.

Claims 91, 117, 118, and 124, and new claims 172-176 are subject to examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Allowable Subject Matter

Applicant's elected species H-Ala-D-Cha-Azc-D-Tyr-Har-NH_2 has been previously indicated as an allowable species. It is noted, however, that no instant claims are directed towards the specific species.

Priority

Applicant's arguments with regards to the benefit of priority to the foreign are persuasive, and the objection is herein withdrawn.

Response to Amendment/Arguments

Applicant's arguments and amendments, filed June 28, 2005, with regards to claim 124 being a substantial duplicate of claim 117 and the rejection of claims 91, 117, 118, and 124 under 35 USC §§ 102(b) and 112, 2nd paragraph, been fully considered and are persuasive. The rejections and objections have been withdrawn. However, new grounds of rejection are set forth below, necessitated by Applicant's amendments to the claims. Specifically, the scope of claim 91 has been broadened.

Applicant's amendments to the claims render the previous examiner elected species unreadable upon the claims. The examiner has expanded the search to read upon the following species:

H-Gly-Arg-MCA, MCA is 7-amido-4-methylcoumarin. The compound reads upon **claims 91, 118, and 176**. The compound is a species where the 'molecule is shortened at the C-terminus' by 'not less than one amino acid', specifically, shortened by 4 amino acids (i.e.- aa^5 and aa^6 remain).

Claims 117, 124, and 172-175 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected specie, there being no allowable generic or linking claim. Please note, although claims 117, 124, and 172-175 stand as withdrawn from consideration, they have been examined insofar as 35 USC § 112 and formalities, for Applicant's benefit. This does not imply or suggest that the claims have been examined in view of the prior art.

Claims 91, 118, and 176 have been examined on the merits.

New Grounds of Rejection

Claim Objections

Claims 91 and 173 are objected to because of the following informalities:

The amino acid aa^3 in Claim 91, recites "is any arbitrary amino acid, selected from the group". A group is not 'arbitrary', as it is specifically defined by the members therein. Applicant is suggested to strike the recitation 'any arbitrary amino acid'.

The parenthetical expressions in claim 91, e.g. Y^2, species a) to f) are improper, as although they are recognized as further describing the connectivity, text within parentheses are considered to be 'optional'. Removal of the parenthesis

The species 'i)' in claim 173 recites 'praline', which is a camelized nut. 'Proline' is an amino acid.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 91, 117, 118, 124, and 172-176 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application, of the specific subject matter later claimed by him. The courts have stated:

> "To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); *In re Gostelli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, no that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966." *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include "level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient." MPEP § 2163.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In *Regents of the University of California v. Eli Lilly & Co.* the court stated:

> "A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *Fiers*, 984 F.2d at 1171, 25 USPQ2d at 1606; *In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279, 284985 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus ...") *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

The MPEP further states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP § 2163. The MPEP does state that for a generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. MPEP § 2163. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP § 2163.

Although the MPEP does not define what constitute a sufficient number of representative species, the courts have indicated what do not constitute a representative number of species to adequately describe a broad generic. In *Gostelli*, the courts determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. *In re Gostelli*, 872, F.2d at 1012, 10 USPQ2d at 1618.

The factors considered in the Written Description requirement are (1) *level of skill and knowledge in the art*, (2) *partial structure*, (3) *physical and/or chemical properties*, (4) *functional characteristics alone or coupled with a known or disclosed correlation between structure and function*, and the (5) *method of making the claimed invention.*

In the instant case, the claims are drawn to Compounds of formula (IV), a pharmaceutical composition or medication of said compound, or a diagnostic. Formula (IV), as drafted in claim 91, can be of a myriad of structures, including the following: water, methanol, any alcohol, methanoic acid, 7-amino-4-methylcoumarin (MCA), dihydrogen (H_2), *p*-nitroanilide (pNA), any alkyl chain, any alkylamine, or any 'connecting chain' (Y1-Y2, because the limits of molecule shortening at the C and/or N termini are not limited); further the compounds can be any amino acid, any dipeptide, any tripeptide, any tetrapeptide, and pentapeptide, and any hexapeptide, with the proviso that when aa^3 and/or aa^6 are present they are defined as required by the claim (L-or D- Cha or Chg; and 'basic amino acid', respectively) ('shortened ath the C-terminus and/or N-terminus by not less than one amino acid).

Further, it is noted, that although dependent claims 172-176 individually limit the scope of a single amino acid position, via Markush groups, the claims do not specifically require that they are part of the compound.

(1) Level of skill and knowledge in the art:

Synthetic methods and formulary methods are well known in the art.

(2) Partial structure:

The claims and specification provide limited structural description for the myriad of compounds embraced by the claims. The compound, in an exemplary embodiment, may be any dipeptide, and in another any tripeptide, with aa^1 being L- or D- Cha or Chg.

In dependent claims, though some elements are defined (e.g. claims 172-176), the structure of the myriad of compounds embraced is not sufficiently described.

(3) Physical and/or chemical properties and (4) Functional characteristics:

The compounds, in one aspect of the invention must be 'medicines' or 'pharmaceuticals' that are 'thrombus-preventing' (*vida infra*, claim 124)and in another 'diagnostics' for an unspecified use. The claims and specification do not describe with sufficient specificity what aspects of the invention provide for any of the embraced compounds to be a 'diagnostic' or which aspects provide for the compounds to be a 'pharmaceutical'/'medicine' which is 'thrombus-preventing'. Furthermore, in another aspect, the compound comprises a 'connecting chain' which is described only as having 1-35 atoms (Y^2), or Y^1 being 'characterized by a backbone consisting of 1 to 32 carbon atoms'.

(5) Method of making the claimed invention:

Methods of making compounds and formulations are known in the art. However, the specification describes methods of making of a limited number of species embraced by the generics, and lacks sufficient variety to describe how one would make the myriad of compounds embraced by the generic claims.

As stated *supra*, the MPEP states that written description for a genus can be achieved by a representative number of species within a broad generic. It is unquestionable that claims 91,

117, 118, 124, and 172-176 are broad generics, with respect to all possible compounds encompassed by the claims. The possible structural variations are limitless to any class of compound, as shown *supra*. It must not be forgotten that the MPEP states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP § 2163. Here, though the claims may recite some functional characteristics (e.g. 'pharmaceutical', 'medicine', or 'diagnostic'), the claims lack written description because there is no disclosure of a correlation between function and structure of the compounds beyond compounds disclosed in the examples in the specification. Moreover, the specification lack sufficient variety of species to reflect this variance in the genus beyond the limited number of closely related peptide compounds. While having written description of the previously elected species, and compounds identified in the specification tables and/or examples, the specification is void of any peptides, organic molecules that qualify for the functional characteristics claimed as the 'medicine', 'pharmaceutical', or 'diagnostic'.

The description requirement of the patent statue requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736, F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.") Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and

does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

Claims 117, 118, and 124 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for making compounds of the examples and specification, does not reasonably provide enablement for making pharmaceuticals, medicines, or diagnostics, for the myriad of compounds embraced by the generic claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirements of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir., 1988). The court in Wands states, "Enablement is not precluded by the necessity for some experimentation, such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue', not 'experimentation'" (Wands, 8 USPQ2sd 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations" (Wands, 8 USPQ2d 1404). Among these factors are: (1) the nature of the invention; (2) the breadth of the claims; (3) the state of the prior art; (4) the predictability or unpredictability of the art; (5) the relative skill of those in the art; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

While all of these factors are considered, a sufficient amount for a *prima facie* case is discussed below.

(1) The nature of the invention and (2) the breadth of the claims:

The claims are drawn to a medication, a pharmaceutical, or a diagnostic, of a compound of formula (IV). Thus, the claims taken together with the specification imply that one could make a pharmaceutical or medicine which is thrombus-preventing, or diagnostic for any purpose with any one of the myriad of compounds embraced by the broad generic claims. The myriad of compounds embraced by the claims have been described *supra*.

(3) The state of the prior art and (4) the predictability or unpredictability of the art:

Methods of formulating medicaments, diagnostics, and pharmaceuticals are known.

With regards to the myriad of compounds embraced by the claims, however, the effect of amino acid substitution in a peptide or protein, the art is unpredictable.

RUDINGER (J. Rudinger. In: Peptide Hormones, JA Parsons, Ed. (1976) 1-7) teaches that, "The significance of particular amino acids and sequences for different aspects of biological activity cannot be predicted *a priori* but must be determined from case to case by painstaking experimental study." (Page 6).

Further, the effects of a single amino acid substitution can have substantial effects on proteins in structure and/or function and are exemplified by the difference between hemoglobin (Hb) and abnormal hemoglobins, such as sickle-cell hemoglobin (HbS). VOET (D. Voet and J.G. Voet. Biochemistry, 2nd Edition.(1995), pages 235-241) teaches that the mutant hemoglobin HbE [Glu B8(26)β → Lys] has, "no clinical manifestations in either heterozygotes or homozygotes." (Page 235). Further, Hb Boston and Hb Milwaukee both have single point mutations which result in altered binding affinity and ineffective transfer from the Fe(III) to Fe(II) oxidation state. Conversely, a single point mutation in Hb Yakima results in increased oxygen binding by the heme core, and in Hb Kansas, the mutation causes the heme center to remain in the T state upon binding oxygen (rather than structurally rearranging to the R state). (Page 236).

HbS is a single point mutation, Val → Glu A3(6)β (Page 236), which results in deformation and rigidity of the red blood cell. The mutation also provides protection against most malarial strains.

Further, SMILEK (D.E. Smilek, *et al.* Proc. Natl. Acad. Sci. USA (1991) 88, pages 9633-9637) teaches that a single amino acid substitution in the myelin basic protein peptide, "confers the capacity to prevent rather than induce EAE even after peptide-specific encephalitogenic T-cells have been activated." (Abstract).

MESSER (W.S. Messer, "Vasopressin and Oxytocin", web document updated 4/3/2000; http://www.neurosci.pharm.utoledo.edu/MBC3320/vasopressin.htm; 5 pages) that two compounds, vasopressin [cyclo(1-6)CY**I**QNCP**L**G-NH_2] and oxytocin [cyclo(1-6)CY**F**QNCP**R**G-NH_2] differ by only two amino acids, as indicated, yet they have different functions. Vasopressin (antidiuretic hormone, ADH), "at low doses controls the resorption of water by the distal tubules of the kidneys and regulates the osmotic content of blood... [and at] high doses, ADH causes contraction of arteriles (*sic*) and capillaries, especially those of the coronary vessels, to produce localized increases in blood pressure." (page 1).

Oxytocin, on the other hand, stimulates smooth muscle contraction in the uterus, mammary glands, and the "alveoli and larger sinuses of the mammary glands to make readily available milk" (page 1).

Further, ADH has 2 types of receptors (V1 and V2) found in vascular smooth muscle and the kidney, while oxytocin has one type of receptor found in uterine and mammary smooth muscle.

Given that the effect of amino acid substitution is highly unpredictable, and can produce an effect opposite or different to that which is desired, it flows logically that one would be unduly burdened with experimentation to determine the effect of amino acid substitution(s) in a peptide or protein, with regards to structure, function, or physical/chemical properties. One

would not know if a compound were capable of functioning in the context of the invention without undue experimentation, and given the unpredictability in the art, it is likely that the compounds would have an opposite effect than that which is desired, e.g. formulation of a poison rather than a medicine, or a thrombus-producing compound rather than an thrombus-preventing compound.

Since the means for predicting the effect of amino acid substitution remains largely unsolved, means for making a medicament or pharmaceutical that is a thrombus-preventing formulation, or diagnostic is highly unpredictable.

(5) The relative skill of those in the art:

The relative skill of those in the art is high.

(6) The amount of direction or guidance presented and (7) the presence or absence of working examples:

The specification has provided limited examples of making diagnostics from a series of related peptides (Examples), and methods of making pharmaceuticals and medicines are known in the art. However, the specification does not provide guidance on how one would select which aspects of the myriad of compounds to function as medicines or pharmaceuticals that are thrombus-preventing, or diagnostics. Additionally, the specification does not teach what the myriad of compounds embraced by diagnostics would be useful for diagnosing.

(8) The quantity of experimentation necessary:

Considering the state of the art as discussed by the references above, specifically with regards to the unpredictable effect of amino acids, and the lack of guidance provided in the specification, specifically with regards to the how one would make and use the compounds as medicines, pharmaceuticals, or diagnostics, one of ordinary skill in the art would be burdened with undue experimentation to make the myriad of compounds into formulations that would function in the context of the invention.

It is the Examiner's position that one skilled in the art could not practice the invention commensurate in the scope of the claims without undue experimentation.

The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 91, 117, 118, 124, and 172-176 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 91 is vague and indefinite for the following reasons:

The claim recites "A compound of formula (IV)", however at the end of the claim, the claim recites that one or more amino acids may be removed from either end (paraphrased). The structure of Formula (IV) is an absolute, and cannot be modified by removal of internal elements. Therefore, it is confusing, how one could remove the internal components of a structure and retain the structure of formula (IV).

Claims 172 and 173 lack antecedent basis. Claims 172 and 173 depend from claim 91, however claim 91 does not allow for aa^1 or aa^2 to be absent, i.e.- 'a chemical bond'.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 91, 118, and 176 are rejected under 35 U.S.C. 102(b) as being anticipated by SVENDESEN (US Patent4,440,678), in view of BASTIN (R.J. Bastin, et al. Org. Proc. Res. Dev. (2000) 4, 427-435).

The claims, in view of the examiners species election which was necessitated by Applicant's amendments, are drawn to H-Gly-Arg-MCA, pharmaceutical salts thereof and a diagnostic comprising said compound.

Svendensen teaches H-Gly-Arg-MCA·2HBr (column 10, line 53). Svendensen teaches that the compounds of the invention are "used for assaying certain enzymes, and in particular, factor Xa" (abstract).

HBr is a pharmaceutically acceptable salt (see Bastin, Table 1, page 428), thus meeting the limitation of 'pharmaceutically acceptable salt'. The amino acids in position 5 and 6 are 'any' and 'basic', specifically Gly and Arg. Y^2 is MCA, Y^1 is H.

Because the claims do not require any additional component in the 'diagnostic', because the compound of Svendesen is that which is instantly claimed, and because Svendesen teaches the compounds are used in assays, the compound must inherently be a diagnostic, that is a 'diagnostic' for enzyme assays.

Nonelected Claims

This application contains claims drawn to an invention nonelected without traverse on March 11, 2005. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action, for the reasons set forth at the beginning of this action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew D. Kosar whose telephone number is (571)272-0913. The examiner can normally be reached on Monday - Friday 8am-430pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571)272-0974. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Andrew D. Kosar, Ph.D.
Art Unit 1654

CHRISTOPHER R. TATE
PRIMARY EXAMINER